

Notice of Allowability	Application No.	Applicant(s)	
	10/050,190	TWARDZIK ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/17/04.
2. ☒ The allowed claim(s) is/are 3-7 and 18-22, renumbered as 1-10, respectively.
3. ☒ The drawings filed on 15 January 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>1/15/02, 11/26/02, + 5/17/04</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
|---|--|


BRENDA BRUMBACK
 SUPERVISORY PATENT EXAMINER
 TECHNOLOGY CENTER 1600

EXAMINER'S AMENDMENT & REASONS FOR ALLOWANCE

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lisa A. Haile on 10/27/04.

An examiner's amendment to the record appears below.

In the specification:

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Page 1, line 1, inserted after "August 17, 2000":

--, now abandoned--.

Page 1, line 3, inserted after "August 19, 1999":

--, now abandoned--.

Page 26, line 8, inserted after "1999":

--, now abandoned--.

In the claims:

Canceled claims 8-17.

Amended the following claims:

Claims 1-2 (previously canceled).

3. (Currently Amended) A method for ~~treating, regenerating or repairing a~~
tissue inducing the activity of CD34 positive progenitor cells of a subject *in vivo*[,]
in need of such treatment, comprising:
contacting a tissue with a TGF- α 57 polypeptide (SEQ ID NO:3), ~~a TGF- α -related~~
~~polypeptide, a fragment or a mimetic thereof prior to, contemporaneously with, or~~
~~subsequent to a tissue injury~~ in an amount effective to induce stem cell or
precursor cell proliferation, migration, or differentiation, ~~at the site of injury~~
thereby inducing the activity of CD34 positive progenitor cells of a subject *in vivo*
in need of such treatment ~~treating, regenerating or repairing the tissue.~~

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4. (Currently amended) The method of claim 3, wherein the contacting is by continuous infusion of the a TGF- α 57 polypeptide (SEQ ID NO:3), ~~fragment or mimetic.~~

5. (Currently amended) The method of claim 3, wherein the contacting is by bolus or single administration of the TGF- α 57 polypeptide (SEQ ID NO:3), ~~fragment or mimetic.~~

6. (Currently amended) The method of claim [4] 3, wherein the tissue is a musculoskeletal tissue, a gastrointestinal tissue, or a urogenital tissue.

7. (Currently amended) The method of claim [5] 3, wherein the tissue is selected from the group consisting of a musculoskeletal tissue, a gastrointestinal tissue, a urogenital tissue, and a neurological tissue.

Claims 8-17 canceled.

18. (Currently amended) The method of claim 3, wherein the ~~tissue injury~~ need of such treatment results from cytotoxic or immune-suppressing therapy.

19. (Currently amended) The method of claim 3, wherein the ~~injury~~ need of such treatment results from ARC or AIDS.

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20. (Previously presented) The method of claim 3, wherein the subject is a mammal.

21. (Previously presented) The method of claim 20, wherein the mammal is a human.

22. (Currently amended) The method of claim 3, wherein the contacting is at the site of the tissue ~~injury~~.

Claims 23-72 (previously canceled).

2. The following is an examiner's statement of reasons for allowance: the closest prior art of record is US 4,863,902 (Amagase et al., "Amagase", reference DP on PTO-1449). Amagase teaches a method comprising the administration of TGF- α in combination with chemotherapy to treat cancer. Amagase does not teach or reasonably suggest the use of the specific TGF- α -related polypeptide TGF- α 57 (SEQ ID NO:3) in combination with chemotherapy to treat cancer.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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3. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961. The fax phone number for this Group is currently (703) 872-9306.



Stephen Gucker

October 27, 2004



BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600